

## **F. 510(k) Summary**

Submitters information: Lhasa OMS, Inc.  
230 Libbey Parkway  
Weymouth, MA 02189

Contact Person: Mark W. Sheehan      Telephone: 781-340-1071 ext. 20  
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Date Summary Prepared: June 10, 2005

### **Device name:**

Proprietary name:	E-Stim II
Common or usual name:	Portable transcutaneous electrical nerve stimulator (TENS)
Classification name:	Transcutaneous electrical nerve stimulator, Class II, 21 CFR 882.5890.

Legally marketed device for substantial equivalence comparison:  
Well- TENS, K002874

### **Description of the device:**

The device consists of a battery powered portable instrument with dual channel outputs connected to lead wires and electrodes. Setting the output switch and the intensity controls will deliver the desired stimulation. Adjusting the frequency control will change the stimulation as well. Treatment continues as long as the intensity control dial switch is on.

### **Intended use of the device:**

The E-Stim II is intended for use in the symptomatic relief of chronic intractable pain, post traumatic acute pain, and post surgical pain. It is designed for use by a therapist. This is a prescription device and should be used under continued medical supervision. The intended use of the Well-Tens is identical. It does not have curative value, but relieves pain symptoms.

The E-Stim II cannot be used transcerebrally, in the carotid sinus area or during pregnancy. Patients suspected of having heart disease should consider adequate precautionary measures prior to administration. Severe spasm of the laryngeal and pharyngeal muscles may occur when the electrode is placed across the neck or mouth. This may be enough to close off the airway. Stimulation will inhibit the output of some demand cardiac pacemakers and therefore, is not recommended for patients with this type of pacemaker.

Electrical nerve stimulation is a symptomatic treatment, and as such may suppress the progress of pain which would otherwise serve as a protective influence on the outcome of a disease process. The potential for physical

and/or psychological dependence upon nerve stimulation as a means of relieving pain has not been determined.

It has been noted that some patients find the sensation of electrical stimulation extremely unpleasant and should probably be excluded from further use of the stimulator.

Technological Characteristics:

Both devices use one 9 volt battery. During stimulation, the electrical output for both devices is square waveform pulses. Details of electrical output are different but new safety concerns are not raised by the differences. Controls on each device regulate stimulation intensity and frequency. Material composition of the electrodes and the lead wires is identical.

Standards:

The E-Stim II has been designed and tested to conform to the following standards:

ISO 14971:2000

EN ISO 10993.1:1997/EN ISO 10993.5:1999/

EN ISO 10993.10:2002

EN 60601-1:1990+A1:1993+A2:1995+A13:1996/

IEC 60601-1:1988+A1:1991+A2:1995

EN 60601-1-2:2001/IEC 60601-1-2:2001

EN 980:2003

Applicable testing criteria from the AAMI standards for Transcutaneous Electrical Nerve Stimulators NS4: 1985 for Well-TENS.



SEP - 6 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Mark W. Sheehan  
Lhasa OMS, Inc.  
230 Libbey Parkway  
Weymouth, Massachusetts 02189

Re: K050435  
Trade/Device Name: E-Stim II  
Regulation Number: 21 CFR 882.5890  
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief  
Regulatory Class: II  
Product Code: GZJ  
Dated: June 3, 2005  
Received: June 8, 2005

Dear Mr. Sheehan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

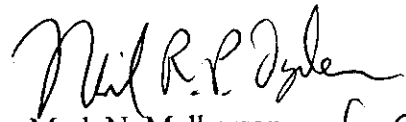
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Mark W. Sheehan

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson *for*  
Acting Director  
Division of General, Restorative,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**G. Indications for Use**

**Indications for Use**

510(k) Number (if known): K050435

Device Name: E-Stim II

Indications For Use: The E-Stim II is intended for use in the symptomatic relief of chronic intractable pain, post traumatic acute pain, and post surgical pain.

Prescription Use   X  

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

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**Division of General, Restorative,  
and Neurological Devices**

510(k) Number   K050435